

Ontario Ministry of Health
Submission of Patient Evidence:
Freestyle Libre 2 (FSL2) Flash Glucose Monitoring System

Section I – Author Information

Date May 25, 2021

Drug and Indication FreeStyle Libre 2 (FSL2) Flash Glucose Monitoring System for type 1 and type 2 diabetes

Author Amanda Sterczyk

Patient Advocacy Group Diabetes Canada

Street No. & Name 1300-522 University Ave.

City/Province Toronto, ON

Postal Code M5G 2R5

Telephone No. 416.363.3373

Email Address Amanda.Sterczyk@diabetes.ca

Section II – Conflict of Interest Declaration: *The author and the patient group must declare any potential conflicts of interest that may influence or have the appearance of influencing the information submitted. Examples of conflicts of interest include, but are not limited to, financial support from the pharmaceutical industry (such as educational/research grants, honoraria, gifts, and salary), as well as affiliations or personal/commercial relationships with drug manufacturers or other interest groups.*

Diabetes Canada receives unrestricted educational grants from, and among others, manufacturers/vendors of medications, supplies, and devices for diabetes and its complications. These funds help the organization support community programs and services for people living with diabetes and contribute to research and advocacy efforts across Canada. No sponsor was involved in developing the content of this submission.

Section III – Impact of the Disease/Condition: *What symptoms and problems do patients have as a result of the disease/condition? How does the condition affect day-to-day life? For example, are there activities that patients are not able to do as a result of the condition?*

The data reported in this submission are drawn from the results of two surveys:

- In August 2020, Diabetes Canada (in collaboration with JDRF Canada and Type 1 Together) surveyed the diabetes community about glucose monitoring. A total of 873 Canadians completed the survey, with the majority of participants living in British Columbia (34%, n=294), Ontario (32%, n=280), Alberta (13%, n=114), and Saskatchewan (5%, n=45). Of the 873 respondents, 54% (n=472) identified as living with type 1 diabetes, 41% (n=361) identified as being a caregiver to someone living with type 1 diabetes, 4% (n=36) identified as living with type 2 diabetes, and 0.5% (n=4) identified as being a caregiver to someone living with type 2 diabetes.
- In March to May 2021, Diabetes Canada solicited input on the Freestyle Libre and Libre 2 via social media. A total of 468 Canadians completed the survey, with most participants living in Ontario (93%, n=435). Of the 468 respondents, 55% (n=257) identified as living with type 2 diabetes, 40% (n=186) identified as living with type 1 diabetes, 4% (n=20) identified as a caregiver to someone living with type 1 diabetes, and 1% (n=5) identified as being a caregiver to someone living with type 2 diabetes. This second survey was undertaken to answer specific questions

posed by Ontario Health regarding finger prick testing with both the Freestyle Libre and Libre 2, as well as users' perceptions of advantages and disadvantages of these products.

Diabetes is a chronic and progressive disease with no known cure. Type 1 diabetes occurs when the pancreas is unable to produce insulin. Type 2 diabetes occurs when the pancreas does not produce enough insulin or when the body does not effectively use the insulin that is produced. Common symptoms of diabetes include extreme fatigue, unusual thirst, frequent urination, and weight change (gain or loss).

Diabetes requires considerable self-management, including eating well, engaging in regular physical activity, maintaining a healthy body weight, taking medications (oral and/or injectable) as prescribed, monitoring blood glucose, and managing stress. Glucose levels outside the target range are serious and problematic. Low blood glucose can precipitate an acute crisis, such as confusion, coma, and/or seizure that, in addition to each being potentially dangerous as an isolated event, may also contribute to a motor vehicle, workplace, or other type of accident that can cause harm. High blood glucose over time can irreversibly damage blood vessels and nerves, resulting in blindness, heart disease, kidney problems, and lower limb amputations, among other issues. The goal of diabetes management is to keep glucose levels within a target range to minimize symptoms and avoid or delay complications.

Hypoglycemia is a major challenge for people living with type 1 diabetes trying to achieve glycemic targets. Diabetes Canada's 2018 Clinical Practice Guidelines define hypoglycemia as: 1) the development of autonomic or neuroglycopenic symptoms; 2) a low plasma glucose level (<4.0 mmol/L); and 3) symptoms responding to the administration of carbohydrates. It can be severe and can result in confusion, coma, or seizure, and require the assistance of others to bring blood sugar levels back into their target range. If untreated, it can be fatal. Frequent or severe hypoglycemia can negatively impact one's quality of life and bring about fear of future hypoglycemia. This fear can result in some people, unconsciously or intentionally, running their blood sugars high to avoid experiencing an episode of hypoglycemia. This puts them at increased risk of future complications due to elevated blood sugar levels. Many people with diabetes develop an inability to feel symptoms of hypoglycemia over time (known as hypoglycemia unawareness). This can prevent them from taking action to treat hypoglycemia, particularly when they are sleeping, which puts them at significant risk of severe hypoglycemia. For these people, advanced glucose monitors—which have alarms that can wake the user to warn them of impending low blood sugars—can be life-saving.

Participants' Experiences with Hyperglycemic and Hypoglycemic Events:

People living with type 1 and type 2 diabetes frequently experience episodes of hyperglycemia (high blood sugar) and hypoglycemia (low blood sugar). Left untreated, hyperglycemia and hypoglycemia can increase the risk of developing a range of short- and long-term complications, including coma and death. Of the survey respondents from across Canada (n=873), 43% (n=377) reported experiencing more than one hyperglycemic event (high blood sugar) a week and a further 42% (n=364) reported experiencing more than one hyperglycemic event a day. Furthermore, 56% (n=476) reported experiencing more than one hypoglycemic (low blood sugar) event a week, 20% (n=168) reported experiencing more than one hypoglycemic event a day, and 19% (n=160) reported experiencing two to four hypoglycemic events a month.

Participants' Experiences with Mental Health Conditions:

Mental health conditions related to the diagnosis and/or self-care demands of diabetes often have a negative effect on many aspects of diabetes management and glycemic management. People living with diabetes are at greater risk of developing mental illnesses and poor mental health compared to people without diabetes. Respondents from across Canada (n=873) reported experiencing a range of mental health problems including (in order of prevalence):

- Diabetes distress (74%)
- A general sense of worry and/or anxiety (73%)
- Worry about not being able to afford diabetes medications and supplies (71%)
- Fear of hypoglycemia (67%)
- Diabetes indifference and/or burnout (65%)
- Emotional exhaustion (62%)
- Loss of sleep due to worrying about diabetes (59%)
- Negative social interactions due to diabetes (53%)
- Alarm fatigue (47%)
- Depression (45%)
- Forgetting to check glucose levels (43%)
- Forgetting to take medication (36%)
- Diabetes defiance (28%)
- Post-traumatic stress disorder (PTSD) (16%)

Participants' Experiences with Diabetes-Related Complications and Comorbidities:

Respondents from across Canada (n=873) reported experiencing a range of diabetes-related complications and comorbidities including (in order of prevalence):

- Other autoimmune disorders (39%)
- High blood pressure (27%)
- Eye problems (25%)
- High cholesterol (25%)
- Nerve damage (22%)
- Other drugs that impact my glucose control (19%)
- Foot problems (16%)
- Arthritis (16%)
- Kidney symptoms or disease (11%)
- Mental health conditions (9%)
- Heart problems (7%)
- Hormones¹ (5%)
- Damage to blood vessels or brain (4%)
- Digestive issues (3%)
- Brain injury/neurological conditions (3%)
- Digestive issues (2%)

¹ Includes puberty, growth, hormonal issues, menopause, as described by respondents.

The people who were living with conditions in addition to diabetes included 232 Canadians (27%). These other medical conditions did in fact impact their ability to manage their diabetes and their blood glucose. Common themes reported were:

- Glucose levels fluctuate due to other conditions and their medications (e.g., stress, steroids for other conditions, food requirements for celiac disease, all cause increases to blood sugar).
- Episodes of severe hypoglycemia are masked by other symptoms/conditions, such as a seizure being due to an episode of extreme hypoglycaemia rather than epilepsy.
- Some conditions and their medications impact the body's ability to absorb glucose (carbs) and/or insulin.
- It's a vicious cycle: other conditions lead to increased stress, which raise glucose levels, leading to other conditions.
- Life is more complex: more doctors' and lab appointments cause disruptions to work and homelife.
- Exercise would help patients manage their diabetes, but their other health conditions limit their ability to exercise.
- Impaired manual dexterity (e.g., related to arthritis) impacts ability to complete finger prick testing.

Survey respondents highlighted how diabetes impacts every aspect of their day-to-day lives: financial, physical, emotional, social, and professional. It is a condition that requires constant monitoring, 24 hours a day, seven days a week, making it feel like they have another full-time job. Diabetes management is time consuming, taking an average of 14 to 20 hours per week to manage, and there is never a chance for a break from diabetes: changing sites, constantly giving needles, staying on top of everything that impacts glucose levels (e.g., food, exercise, stress, illness), etc. The variable nature of diabetes means that management success changes day to day. Insulin delivery does not control diabetes, it's not a cure just a treatment, and there exists much room for human error.

Constantly being hooked up to something, having to lug so many supplies around is both inconvenient and cumbersome for survey respondents. The constant pokes from finger pricks and needles are painful. People with diabetes of all ages experience social stigma in public when they are required to test their blood glucose and administer insulin. This leads to discrimination, an inability to fully participate, and a loss of spontaneity (e.g., kids cannot just be kids).

Diabetes is a disease that places many burdens on patients and their families. The mental health burden of diabetes causes stress and anxiety. The high cost of diabetes medicines, supplies, and devices is a financial burden, and respondents report inadequate coverage by private insurers and provinces. Caregivers, especially mothers of children with type 1 diabetes, must change their lives to help with diabetes management: not sleeping at night, quitting jobs to be present at school when school staff refuse to test children or deliver insulin. In essence, the disease ends up taking over family life. People with diabetes experience stress due to nighttime episodes of hypoglycemia, and/or worrying about the ability to afford diabetes supplies. Diabetes also impacts family and life decisions: some women with type 1 diabetes choose not to have children—some for fear of passing on the genetic predisposition to diabetes and others worry about being able to care for a baby while managing their diabetes. Many respondents indicated that they had to choose to spend money on diabetes supplies over taking family vacations.

For adults living with diabetes, there is also a professional burden: some people are unable to take employment opportunities, they are often worried about experiencing episodes of hypoglycemia at work (and may subsequently decide to endure long-term periods of hyperglycemia while at work), or they may be forced to choose a job based on the organization's benefits plan and not the actual role. Diabetes imparts a physical burden on people of all ages. More planning is required for exercise and physical play, some place limits on their activity to manage their diabetes. Also, on the physical side, other health issues and complications due to diabetes increase health-care needs, wounds take longer to heal, it takes longer to recover from illnesses (e.g., colds), and it negatively impacts sleep (e.g., worry about lows, finances, etc.).

Below are select quotes from Ontarians, describing how diabetes impacts their day-to-day lives:

"A constant worry of going low during the night and high during the day."

"Affects every minute of every day. We have to monitor every morsel of food my daughter ingests. We check her every hour of every night, we haven't had a full nights sleep in 4 years and are constantly exhausted."

"Constant struggle with diet & exercise, while working full time, taking care of a family, constant planning and reminders, insulin calculations, trips to pharmacy for supplies."

"Daily stressor, gives a lot of anxiety at times, and added mental and physical burden. Extensive burnout from having to be aware 24/7 which has impacted other areas of my life."

"Diabetes is a 24/7 life or death job. It is exhausting. You may have one day of perfect readings but then the next day could be completely different. It requires extensive planning to do anything- whether it is a vacation or simply deciding what to have for lunch. I am lucky to have an excellent health plan that allows a brief respite from this management- in the form of my insulin pump and glucose monitor."

"Diagnosed with Type 1 at age 62yrs... not even a cavity in my entire life until then. Steep learning curve to understand T1D. Started with MDI, now with a pump. I am constantly reminded I am T1D but am trying to normalize it."

"Every single day is scary. My son can die every single day if we make the incorrect decision. He always has to plan. Every day. For school, for sports, for activities. He can never be a spur of the moment type of person."

"Hypo-unaware. Seizure due to low blood sugar. Anxiety and stress affecting bg's - lots of highs since pandemic started."

"It has changed the way he eats and what he eats and can put limits on his physical activities."

"Diabetes has affected my daily life by limiting me in the activities I can participate in. At times when I was first diagnosed, for the first year, I felt like it controlled my life (i.e., I wouldn't eat out, eat certain things, etc.). Initially when I was diagnosed, I grieved my old life a lot and just wished I could go back in time to prediabetes life."

“Well, it’s affected every part of our lives - financially, physically, emotionally, and professionally. Our daughter was diagnosed at 3 years old. Since then, we’ve lost thousands of hours of sleep and finger poked her over 10,000 times, written countless diabetes management plans to help childcare and school staff help keep her safe. It’s one more layer of complexity we have to consider before she does anything even as basic as having a play date with another child, attending an organized birthday party where sugar-rich food are served, etc. At times it’s utterly overwhelming.”

Treatment outcomes that matter most to patients: *What are the most important aspects of the condition that patients would like to see addressed by treatments? In terms of treatment efficacy and side effects, what are patients getting from the existing treatments and what would patients like new treatments to do differently? Are there other practical implications to be considered in determining the value of a treatment? For example, how do treatments impact the patients’ or caregivers’ daily routine or lifestyle? In addition to the device cost, are there other financial implications to patients or caregivers (e.g., travelling cost, time away from work, drug disposal issues, drug administration supplies)?*

Patients and their caregivers told us that advanced glucose monitors are both lifesaving and life-changing, improving physical and mental health, reducing the financial and societal burden of this disease. In fact, many respondents felt that it is more important to cover glucose monitoring devices than insulin pumps. People affected by diabetes strongly believe that the cost of funding devices—what some respondents deemed short-term pain for public payers—should be considered against the potential for cost savings of the reduction in long-term complications from diabetes—or the long-term gain of glucose monitors to the health-care system. Finally, they believe that the cost of flash and continuous glucose monitoring devices is comparable to test strips, and that all are tools to better manage the disease. They all have value and different people prefer different options, so they want to be given the choice of glucose monitoring system, informed by discussion with their health-care provider.

Respondents from across Canada (n=873) reported having the following expectation for glucose sensors (in order of prevalence):

- Improves A1C (93%)
- Reduces risk of episodes of hypoglycemia (92%)
- Improves quality of life (89%)
- Reduces risk of episodes of hyperglycemia (88%)
- Ease of use (87%)
- Provides confidence in glucose readings (85%)
- Increases the amount of time glucose levels remain in target range (83%)
- Reduces disruption to lifestyle (80%)
- Maintains target glucose levels (78%)
- Improves health outcomes (78%)
- Allows them to share glucose readings with diabetes health-care team and/or diabetes specialist team (73%)
- Correlates well with blood glucose tests (63%)
- Allows them to share glucose readings with their caregiver (59%)
- Allows them to go days without blood glucose testing (56%)
- Integrates with their insulin pump (53%)

- Reduces number of visits to the hospital (46%)

Regardless of type of device that respondents have used or are currently using, commonalities emerged in the themes reported:

- A device for monitoring glucose is better than self-monitoring blood glucose with finger prick testing.
- They are better able to manage their diabetes: improved blood glucose management, better health outcomes, improved A1C.
- Their quality of life relating to diabetes management has also improved: more freedom and flexibility, less stress and worry, more peace of mind and relief.

People with diabetes and their caregivers have an A+ list of what is important to them in choosing a glucose sensor:

- Accuracy
- Alarms (most yes, a small number no)
- Affordability
- All-in-one, i.e., closed-looping with insulin pump
- Attachment - stays on longer, comfortable, waterproof, no adhesive side effects
- Appearance - small, discreet, can attach anywhere on body
- Automatic readouts/shutoff
- Access to data (share with others)
- Apps
- Arrows - to show if trending high or low

And it comes through in their expectations of new devices, as they become available in Canada:

- Enhance management of diabetes: keep glucose levels in range, reduce A1C, reduce potential for long-term complications, prevent need for medical intervention.
- Improve quality of life, reduce worry/stress, improve mental health.
- Accuracy of readings, reliable data.
- Technology integration: closed looping with insulin pump, all-in-one device, or better integration with other technology (phones, watches, apps).
- Access for all (through provincial and/or private plans) or at least affordable by cost reductions from manufacturers.
- Device: smaller device, lasts longer, rechargeable, waterproof.
- Finger prick testing becomes obsolete.
- Patient choice on right product/device for them, faster approval in Canada (new devices or updates), more options available in the market.

On the positive side, respondents indicated that use of insulin pump and glucose monitoring technology reduced the burden of disease. Glucose monitoring devices have allowed life to be more manageable and enjoyable, which itself helped contribute to better glycemic management. With these technologies, users' glucose levels are better-managed, insulin delivery can be fine-tuned, and users experience more time-in-range, better A1C results, and decreased side effects and long-term complications. The technology increases their flexibility, and they experience less hassle with quick, discreet, convenient glucose checks. It is easier to manage diabetes with the appropriate technology and to live a normal life. This has resulted in reduced anxiety and mental burden, improved safety,

and reduced fear of hypoglycemia (especially nighttime lows). Caregivers reported increased independence for children with type 1 diabetes, improved family life, and overall quality of life.

Below are select quotes from Ontarians, describing how diabetes impacts their financial well-being:

"So much money spent annually that limits my family's vacation ability. We are an above middle income family and WE are pinched by my diabetes costs."

"THE FINANCIAL BURDEN AND FALLING FURTHER AND FURTHER IN DEBT TO STAY ALIVE!"

"CGM and FGM need to be more affordable/attainable to the general public. If we did not have insurance, there is absolutely no way we could afford it for my son. Type 1 diabetes is a complicated condition that should be made as easy as possible to manage to improve quality of life without being a financial burden."

"Living with type 1 diabetes is an immense burden, and many patients fall through the cracks, especially due to the high cost of medical supplies and insulin. Caring for these patients upfront with pump/CGM/insulin coverage is, firstly, a moral obligation. It is unacceptable that someone with a treatable illness should experience a shortened life expectancy due to the insurmountable cost of needed medicines/supplies. Secondly, it just makes good fiscal sense. By helping those with diabetes care for themselves, these patients have better long- and short-term health outcomes. This reduces hospital visits for both acute crises such as hypoglycemic or DKA episodes, as well as serious comorbidities such as heart failure and amputation. Stop letting people with diabetes suffer or even die due to insufficient coverage."

"Need help financially to help with my health now and prevent future expenses with health care. Want to continue to use but the cost out of pocket is so expensive. Not fair the technology is available but need to put myself in debt to survive."

"The cost. We have had to sacrifice in every other area of our lives to be able to afford to continue with the glucose monitor."

Information from patients who have used this device: For patients who have used this device as part of a clinical trial or from a manufacturer's compassionate supply or have purchased it through other means (private insurance or paid out of pocket). What positive and negative impacts does the device have on the condition? Which symptoms is the device best or worst at treating (advantages and disadvantages)? What difference does the device make to patients' long-term health and wellbeing? What are the side effects of the device, which ones are patients prepared to put up with, and which ones do they find unacceptable? How does the device compare with other available treatments in terms of efficacy, side effects and other practical implications (e.g., administration, time, costs)?

Data are reported below on how participants accessed the device (Freestyle Libre). The remaining questions are covered in the questions on pediatric patients, as the information is consistent across all age groups.

Of the respondents from across Canada (n=873), 26% (n=227) reported that they were currently using Abbott flash glucose monitoring, 26% (n=223) reported that they had used it in the past, and

47% (n=411) reported that they have never used it. Of these, only 13 had accessed their device through a provincial health-care plan, 12 of whom reside in Ontario (8% of the Ontario respondents). The other Ontario respondents using a Freestyle Libre reported coverage under private insurance (59%), paying out-of-pocket (27%), through a clinical trial (2%), or from manufacturer's samples (2%).

Respondents across Canada accessed Abbott flash glucose monitoring through the following avenues (in order of prevalence):

- Covered under private insurance (54%)
- Paid out-of-pocket (36%)
- From manufacturer's samples (4%)
- Provincial health-care plan (3%)
- Through a clinical trial (1%)

Respondents reported doing the following to access Abbott flash glucose monitoring (in order of prevalence):

- Cut back on other expenses (48%)
- Stayed in a job to retain medical benefits (33%)
- Choose between basic necessities and diabetes devices (26%)
- Increased debt level (26%)
- Borrowed money from friends and/or family (19%)
- Asked employer to modify medical plan (18%)
- Changed jobs to access medical benefits (9%)
- Held a fundraiser (1%)

For pediatric patients: *What glucose management options are currently used by pediatric patients? Which option is used most often? What are the advantages and disadvantages of each option? What factors influence the choice between these options for pediatric patients?*

The August 2020 survey asked respondents which glucose management options they have used or are currently using, and included self-monitoring blood glucose, or finger prick testing (n=247), flash glucose monitoring (Freestyle Libre; n=94), and continuous glucose monitoring, Dexcom or Medtronic (n=291), for pediatric patients. Currently, Dexcom is being used most often by pediatric patients (n=194), followed by Freestyle Libre (n=79), and Medtronic (n=22).

Freestyle Libre, advantages & disadvantages:

Respondents who use or have used the Abbott flash glucose monitor reported better quality of life, and more independence and confidence. They stated that the device allows them to focus on life, taking less time away from what matters. It improved their ability to focus on work/schoolwork, improved their mental and physical health, and helps with sick day management. Food and meal management has become easier because they can see how different foods affect their glucose levels. Using a flash glucose monitor has allowed them to be more physically active, and they are then able to better manage diabetes with exercise.

They also reported improved glucose control, better A1C results, better health outcomes, fewer episodes of hypoglycemia, elimination of nighttime hypoglycemic seizures, and fewer dosing errors. As a result, people with diabetes and their caregivers experienced better sleep, a sense of relief and peace of mind, as well as less stress and worry. Using the flash glucose monitor made it easier to

track trends, by allowing them to increase the frequency of readings (they can check their glucose levels more often). Fingers healed, and fewer finger pricks translated into less pain and anxiety, as well as an ability to check their glucose levels quicker and more discreetly in public. They described being able to share data more easily with their family and their diabetes team. Caregivers of children with type 1 diabetes reported that the flash glucose monitor makes it easier to check their child's glucose levels while sleeping, at school, or playing sports. It is a less disruptive process that results in better sleep and less anxiety and stress. The caregivers can see patterns (trends) and can then fine-tune insulin dosing, which results in fewer emergencies (episodes of severe hypoglycemia). This method improves the child's independence and freedom, by putting glucose levels in the background instead of the foreground.

Some respondents using the flash glucose monitor preferred it to a continuous glucose monitor (Dexcom or Medtronic) because it lasts longer and does not result in alarm fatigue.

Some respondents indicated they had stopped using the Abbott Freestyle Libre due to cost (unable to afford), no alarms (which caused increased stress), no current trending data (only past 8 hours), pain, allergic reaction to adhesive/skin irritation, lack of constant glucose monitoring, inability to communicate with pump, sometimes inaccurate, scanner is ineffective at end of life, water and intense exercise can cause sensors to fall off. Some of these respondents reported that they preferred a continuous glucose monitoring system.

Very few side effects were reported, most indicated they were only minor, and respondents stated the benefits outweighed the side effects of skin irritation, pain, bleeding, bruising, skin redness, difficulty removing sensor adhesive, sensors that fall off easily, infection, and itchiness.

The following were listed as dislikes of the Abbott flash glucose monitor.

1. Sensor: Sensor obtrusive on arm (bright, visible, not able to place elsewhere), falls off (never stays on), pain at site.
2. Alarms: No alarms/safety features.
3. Technological issues: Having to scan it, doesn't communicate with pumps, not calibrated with finger pricks/blood glucose readings, not accurate compared to CGM/lag time between scan & when number is accurate, no transmitter, not Bluetooth/no communications with phone so a third-party app is required to convert to CGM which adds cost and bulkiness, readings are not continuous.
4. Organizational: Cost, not covered by public payer, company won't replace sensors that malfunction before 14 days, unfriendly customer service.

Some caregivers reported that the Freestyle Libre was easier to use than both finger prick testing and continuous glucose monitors, it's smaller and more affordable.

Below are some select quotes from caregivers about what they prefer with the Freestyle Libre:

"Compared to finger pricks - easier. Less pain for finger poke; kids don't have to stop what they are doing to really swipe and access info (less than stopping to pull out finger prick tester, sterilize finger, prick finger, try and manage test strip and reader; take reading (hope that it worked and don't have to prick again and test again); have friends bothered by blood and what is happening;

wipe blood away; record reading in book; call or text me so he can get help if he requires action (carbs/insulin); pack up; resume his activity."

"I like the lack of alarms, it helped me deal with alarm fatigue that I was experiencing with other systems. I also like that all my data is available on the app and is easy to access which isn't the case with other systems."

"It doesn't beep all the time and interrupt me, but it shows me patterns that I can address after observing them."

"Its smaller than other devices not as bulky."

Data below are reported for two brands of continuous glucose monitors: Dexcom (G6, G5, or G4) and Medtronic (Medtronic Connect, Medtronic Guardian, or Medtronic Enlite).

Dexcom, advantages and disadvantages:

Respondents who used or are using a Dexcom continuous glucose monitor reported better quality of life for themselves and their family, as well as peace of mind, more independence, freedom, and confidence. People described that using the device allows them to focus on life, taking less time away from what matters. Children with type 1 diabetes can focus more on school, playdates, and sleep, and less on their diabetes management. Better sleep for patients and their caregivers instilled a sense of relief in both groups.

The Dexcom CGMs improved glucose control, resulting in better A1C results, better health outcomes, fewer episodes of hypoglycemia, and fewer hospital visits for hypoglycemia emergencies, as well as longer time-in-range by preventing episodes of extreme hyperglycemia. The device makes it easier to track trends, it is a quicker and painless way to check, meaning they can be more discreet in public. They like the slim profile of the sensor and the easy, painless insertion. Fewer finger pricks mean fewer cuts to heal (important, as cuts are slower to help for people living with diabetes), further lessening the disease burden. Respondents reported being able to share data more easily with family members and their diabetes team. They found the alarms help a lot, and the integration with their insulin pump is beneficial. And the longer lasting device is helpful. Some respondents appreciated receiving continuous data every 5 minutes, preferring it to flash glucose monitoring.

Some caregivers of Dexcom users found these devices to be easier to use than self-monitoring by finger prick testing and other glucose monitoring devices. Caregivers reported that Dexcom CGMs were a game changer and life saver, having saved their child's life on multiple occasions by preventing extreme episodes of nighttime hypoglycemia in children who are hypoglycemic unaware. It resulted in better sleep, peace of mind, less anxiety and stress. The device makes it easier to check levels when the child is sleeping, at school, or playing sports. They can see patterns and more information to make better decisions, resulting in fewer emergencies. This further enhanced their child's independence and freedom, resulting in both a happier child and better family dynamics. Caregivers, who are usually mothers, reported being able to return to work outside the home because they no longer need to be always near the child in case of emergency. The device makes it easier to train other caregivers, and reduces the burden on school staff, as well as minimizing interruptions during class time for finger prick testing. Caregivers were positive about the Follow App (which allows up to five people to remotely monitor glucose levels of the person with diabetes, and alarm in case of either hypoglycemia or hyperglycemia), as well as another app that provides

glucose levels while driving. They also appreciated the detailed reports that improved virtual visits with the diabetes care team, alarms for hyperglycemia and hypoglycemia events, as well as the predictive alerts.

Notably, the alarms associated with the device can cause some sleep disturbances, and some people worry about the financial cost of the device. Some respondents reported there were too many alarms—it appears some respondents are not aware that they can turn all, but the urgent low alarm off, or that they can set the alarms to go off at a wider range. They also noted inconsistency with glucose readings compared to finger prick testing—i.e., it is not always accurate. Others indicated that using a Dexcom continuous glucose monitor has not affected their life in a positive way.

The majority of respondents said they experienced no side effects from using the Dexcom CGM. Of those that did list side effects, most indicated they were both minor and infrequent and did not outweigh the benefits. Side effects included skin irritation (most common), pain, itchiness, bleeding. Even less common: bruising, skin redness, skin peeling, scarring, sensors come off.

The following were listed as dislikes of the Dexcom continuous glucose monitor.

1. Sensor: bulky; adhesive - falls off prematurely, causes skin irritation, does not adhere in water; compression lows.
2. Alarms: too many/not enough; too noisy/too quiet; alarm fatigue.
3. Technological issues: sensor fails/lost signals (e.g., drops if too far from transmitter or phone); not compatible with insulin pumps (Omnipod, Medtronic) or phones (Android), app not updated often enough for iOS updates; does not always calibrate/need to do finger pricks to calibrate; long warm-up period after sensor insertion.
4. Organizational (i.e., device company): cost, waste (no recycling), device not rechargeable (hard shut off at three months).

Respondents reported that the Dexcom CGMs improved their glucose control, resulting in better A1C results, better health outcomes, fewer episodes of hypoglycemia, and fewer hospital visits for hypoglycemia emergencies, as well as longer time-in-range by preventing episodes of extreme hyperglycemia. The device makes it easier to track trends, it is a quicker and painless way to check, meaning they can be more discreet in public. They like the slim profile of the sensor and the easy, painless insertion. Fewer finger pricks mean that cuts heal faster, furthering lessening the disease burden. Respondents reported being able to share data more easily with family members and their diabetes team. They found the alarms help a lot, and the integration with their insulin pump is beneficial. And the longer lasting device is helpful. Respondents appreciated receiving continuous data every 5 minutes, preferring it to flash glucose monitoring.

Caregivers of Dexcom users found these devices to be easier to use than self-monitoring by finger prick testing and other glucose devices. Caregivers reported that Dexcom CGMs were a game changer and life saver, having saved their child's life on multiple occasions. It resulted in better sleep, peace of mind, less anxiety and stress. The device makes it easier to check levels when the child is sleeping, at school, or playing sports. They can see patterns and more information to make better decisions, resulting in fewer emergencies. This further enhance their child's independence and freedom, resulting in both a happier child and better family dynamics.

Caregivers reported they like that the Dexcom connects to an insulin pump, the continuous monitoring of glucose readings, the alarms, its accuracy and longevity, that it provides more data, and ease of use.

Below are some select quotes from caregivers about what they prefer with the Dexcom CGM:

"About the same as any other machine. It's great that it monitors at all times and alerts to patterns or fast rises/falls."

"Communicates with pump to prevent lows and will in the future prevent highs once approved by the FDA."

"Haven't used other devices, but it is so much better than relying on finger pricks which are painful and don't give you the overall accuracy needed to make good decisions regarding your health. The libre did not meet our needs as you have to scan it, so it is up to the user. The Dexcom is continuous, even when you are sleeping, which is a relief for the child and parent. We can sleep comfortably knowing that we will be woken up if there is a need. Until we got the Dexcom, I didn't have a worry-free sleep. So, while I might currently have broken sleep because the Dexcom wakes me up, that is so much more preferable than going to sleep worrying I am going to miss an urgent event. The Dexcom has saved us from severe lows as we can treat them in time, as well as severe highs because of pod failures which we might not have known about until it was too late."

"Remote monitoring is life changing for parents of children with Type1 Diabetes."

Medtronic, advantages and disadvantages:

Respondents who used or are using a Medtronic continuous glucose monitor reported being able to check their glucose anywhere, with a small and discreet device, which means being more flexible and spontaneous in life. The continuous data allows for better management during exercise and at night, and they also reported that they found the alarms helpful. The special features of the Medtronic CGMs, such as its connection to their insulin pump that allows them to see glucose trends on the same screen as their insulin bolus and the auto mode (including insulin auto shutoff during episodes of extreme hypoglycemia), were especially beneficial to users. They also appreciated that the devices are waterproof and rechargeable. These features, which improve diabetes glucose management, also allow users the freedom to live life more fully.

Using a Medtronic CGM resulted in better diabetes management. People living with diabetes can see how their blood glucose responds to various activities and are better able to function at work and at home. As a result, they enjoy a better quality of life, they feel more confident with both their diabetes care and their overall health. The device is easy to use, seeing trending data allows for tighter glucose control, fewer episodes of hypoglycemia and hyperglycemia. They experience less stress, anxiety and worry while enjoying a sense of security and peace of mind. Survey respondents reported better sleep and fewer nighttime episodes of hypoglycemia. Caregivers indicated that they could manage the patient's diabetes better, which has increased the child's independence. More information means better decisions, and it is easier to check the child's glucose levels when they are sleeping. This has resulted in better sleep, and less anxiety and stress. The depth of the improvement of quality of life cannot be overstated. The real-world improvement may be even more

pronounced than trial data, as the supports available during a trial are not present and patients depend more on these devices for management support.

Most respondents reported no side effects. Of those that did report side effects, skin irritation was the most common, followed by allergy to adhesive, and sensors that often fell off before expiring. Other cited side effects included pain, bleeding, scarring, bruising, and rash.

The following were listed as dislikes of the Medtronic continuous glucose monitor.

1. Sensor: Skin irritation, rash, bleeding, scarring, sensor bulky/transmitter heavy, falls off (never stays on)/failed cannulas, onerous insertion process, set changes can be painful & traumatic.
2. Alarms: Loss of sleep from alarms, stress of missing alarms at night, too many alarms in the day, not enough alarms at night.
3. Technological issues: Calibrations required with finger prick testing, no app for caregivers to follow, inaccurate, lag time for glucose to match blood glucose, long time to warm up, sometimes disconnects from pump.
4. Organizational: Cost.

Caregivers reported they like that the Medtronic connects to an insulin pump, includes an auto-mode feature, and is the closest thing to a closed-loop system.

Below are some select quotes from caregivers about what they prefer with the Medtronic CGM:

"Allows for auto-mode pumping, what else do I need?"

"Definitely best blood sugar control in 15 years."

"This is only device I trust for my child. The automode basal settings, auto shut off when low, direct link between pump & sensor. I can't imagine choosing another device. Nothing offers the all in one that this system does. My son never hears alarms at night so the fact the pump shuts insulin off on its own is #1 in mind. Dexcom & Abbott do not offer this. I won't switch."

For patients with experience using Freestyle Libre (FSL): What are the advantages and disadvantages of FSL?

Please see pages 9 through 11 for advantages and disadvantages of Freestyle Libre (under pediatric patients section).

Do patients continue to use Blood Glucose Test Strips (BGTS)/finger prick testing with FSL? If so, please indicate when and comment on the rationale for combination use.

Two hundred and ninety-three (63%) respondents to the 2021 survey indicated that they still use finger prick testing with their Freestyle Libre. They do this to check the accuracy of the device reading. This can happen when:

- Physical symptoms do not match the reported reading.
- If glucose levels are changing rapidly.

- At the beginning and/or end of a sensor's life (first and last day in a 14-day period).
- If the Freestyle Libre meter recommends a finger prick testing for calibration or accuracy.
- The reading is out of target range and requires action (carbs for low reading or insulin for high reading, or insulin dosing for meals).
- Health-care provider has recommended finger prick testing when action is needed.
- When it reads LO (i.e., no actual number) so do not know how much fasting-acting carbs are needed.
- To assist with insulin dosing at mealtime.

Some respondents reported that their insurance does not fully cover the Freestyle Libre, so they are forced to switch to finger-prick testing midway through the month. Many people reported that they rarely check with finger prick testing. Some respondents indicated that they combine finger prick testing with their Libre when there is something else happening with their body: as part of sick day management, during their menstrual cycle, or during medical treatments. Other respondents indicated that they use it in combination with finger prick testing every single day, as part of their pre-meal insulin bolus regimen. On the technical side, several individuals reported that they use finger prick testing when their Libre sensor fails. Finally, some survey respondents reported that they find the Libre sensors faulty and unreliable, that sensors fail frequently, and that Libre is not accurate enough to dose insulin (either for meals or for treating highs).

For patients who may have experience using Freestyle Libre 2 (FSL2): What are the advantages and disadvantages? What are the advantages and disadvantages vs. FSL? Do patients continue to use BGTS with FSL2? If so, please indicate when and comment on the rationale for combination use.

Respondents of the 2021 survey listed the following advantages of the Libre 2:

- Optional alarms, which are particularly beneficial for overnight lows.
- Bluetooth connection to smartphone.
- Continuous scanning.
- Sensor is small & unobtrusive.
- Better accuracy.
- More pattern detection.
- No or few finger pokes.
- Can be used with younger children.
- Ability to share data with both family members and the patient's health-care team.
- Less lag time between interstitial and blood glucose values.
- Presents the potential for a closed-loop system with an insulin pump.
- Improved A1C and predicted A1C.
- Better decision-making for health.
- Makes life safer.

And the following disadvantages of the Libre 2:

- The high and low glucose alarms do not provide actual numbers upon which to act. The user still needs to scan the sensor to see the glucose value and check data.
- The Libre 2 does not have a reader and it is not compatible with the Libre 1 reader.
- Not everyone wants to use their smartphone to see their glucose readings and/or carry their phone with them all the time; this step is currently required, as the Libre 2 app is approved in Canada, but the Libre 2 reader is not.

- The cost of a smartphone can be out of reach for some (there is currently no reader for Libre 2, so users need a smartphone to run the Libre 2 app). Some people can't afford to upgrade their phone/carrier/plan to allow app use.
- Having Bluetooth enabled all the time drains a smartphone's battery faster.
- The device is costly and is not covered by public or private plans.
- Libre 2 is not continuous and can't be calibrated like a real-time continuous glucose monitor. Some users are concerned about forgetting to scan their sensor and losing data.
- There is a lot of package waste.
- Only one smartphone device can check glucose readings, and there is no sharing of readings between devices.
- The sensor is not totally waterproof.
- The sensor is susceptible to fails and detachment issues.

Sixty-two percent (n=274) of respondents (n=440) who answered this question indicated they have or will continue to use finger prick testing in combination with the Libre 2.

They do/will do this to check the accuracy of the device reading. This can happen when:

- Physical symptoms do not match the reported reading.
- If glucose levels are changing rapidly or there are large gaps in readings in a short period of time.
- At the beginning and/or end of a sensor's life (first and last day in a 14-day period), or in the case of a sensor malfunction.
- If the Freestyle Libre meter recommends a finger prick test for calibration or accuracy.
- The reading is out of target range and requires action (carbs for a low reading or insulin for a high reading, or insulin dosing for meals).
- Health-care provider has recommended finger prick testing when action is needed.
- When it reads LO (i.e., no actual number) so do not know how much fasting-acting carbs are needed.
- To assess the outcome of alerts and determine if treatments are working.
- To assist with insulin dosing at mealtime.
- During sick day management.

The Freestyle Libre 2 was made available in Canada in mid-March 2021. Many of the 468 respondents to Diabetes Canada's Libre survey had not yet made the switch from Libre to Libre 2. In many instances, individuals were using up their existing stockpile of Libre sensors, as many people purchase supplies for two or more months at a time. As such, only a small handful of respondents had experience using the Libre 2 by mid-May 2021. One respondent indicated that she had received access to Libre 2 while living as a student in another country:

"I have been lucky enough to be using the Libre 2 for two months now, I'm currently living in Scotland where they provide diabetics with the Libre sensor fully funded and now the upgraded version of the Libre 2. I will be moving back to Canada soon and one of my greatest losses will be the loss of using the Libre 2 because I won't have the money to continue it back home. It feels like a step backwards and we really need to keep moving ahead."

Nevertheless, many current Libre users knew about the Libre 2 and were in fact looking forward to switching to the upgraded device. However, others indicated that they did not want to switch to the Libre 2.

Below are selected comments from Ontario respondents to the Libre survey:

"Life in general is so much easier with the Libre. So excited that alarms have been added to Libre 2. If the cost was covered by OHIP+ that would be even better."

"I'm answering on behalf of my brother who is intellectually challenged and T2. He cannot finger prick due to passing out at the thought of a small needle or the sight of blood. I have had him wear a Libre device a couple of times so he can "see" how his eating/activities affect his blood sugar. This is the only way we have to monitor his sugars. Unfortunately, the Libre is not covered by the Ontario Disability Support Program and my brother does not have the funds to purchase them himself, nor I for him. It is the only tool on the market that could assist in monitoring his health."

"I will not be getting a FreeStyle Libre 2 because of the cellphone requirement."

"I will go back to ordering the original Libre after I am done this recent delivery. I hope you will not discontinue those - alternatively, make the new one work with the reader so it is more useful."

"As a 17 year old newly diagnosed, diabetes is very scary. The Libre system has helped my doctors get me on the right amount of insulin. I am always worried about my blood sugars, going low is an awful feeling, the Libre 2 will be so helpful in preventing this with the built in alarm. My parents are self employed and their benefits do not cover anything but insulin. With everything that comes with this disease, it is very expensive. It's really unfair that we have to worry about money and coverage too."

"Today ODB covers me for the Libre 1 sensors. If ODB covers Libre 2, I will get more benefits at the same cost. Receiving alarms for impending lows will greatly reduce the number of lows I experience & make me overall healthier. This will also reduce my health care burden costs for Ontario."

"I absolutely love my Freestyle Libre and I can't wait to try the Freestyle Libre 2. I think it is a brilliant idea and medical device and it has made my life so much easier. Diabetes is a very complicated disease and diabetics and family members need anything we can get to make life a bit easier."

"I have had much better sleep since using the Libre, beginning in Fall 2019. We have the Miao Miao which makes a bridge, sending the data to my phone like a true CGM. Before this I hadn't slept through a night since my daughter was diagnosed in 2012. With the Libre 2, as a I understand, the device will work in the same way, but the technology is integrated."

Conclusion: To maintain glucose levels within their target range, people living with diabetes must continually monitor their glucose levels. The most suitable method of glucose monitoring needs to be determined by the patient in consultation with their medical team. Having access to the most appropriate glucose monitoring device can improve glucose management, avoid short- and long-term complications, and improve a person's experience with this disease by reducing the burden of diabetes.